REMARKS

This document is filed in reply to the Office Action dated May 12, 2004 ("Office Action"). Applicants have amended (i) claims 2, 3, and 5 to promote clarity and (ii) claims 11 and 12 to limit the claimed cells to isolated cells. Support for the amendments to claims 2, 3, and 5 can be found at, e.g., page 3, line 29 through page 4, line 11; and page 9, lines 1-11. Support for "isolated cells" can be found at page 21, paragraph 1 and in Fig. 4.[1] No new matter has been introduced.

The amendments should be entered as they raise no new issues that will require further consideration or search and also do not touch the merits of the application within the meaning of 37 C.F.R. § 1.116(b).

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 3 and 5 for indefiniteness. See the Office Action, page 2, lines 13-16. Applicants have amended these two claims and submit that the amendments have overcome the rejection.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-6, 8-12, 20, and 21 for lack of enablement. See page 3, lines 13-14 of the Office Action. According to the Examiner, the claims, drawn to a retroviral vector, cells containing it, and related systems, read on using the claimed subject matter for gene therapy. It is his position that

> The specification fails to provide adequate guidance and evidence for using a retroviral expression vector ... for cell-specific expression of a desired gene such that the expressed desired gene product would be

[1] The passage and figure disclose several isolated, viral vector-containing cells lines, e.g., T47D, Hela, Chang liver, Huh-7, 293, and LC5 lines. Note that the term "isolated cells" does not have to be set forth verbatim in the specification. In *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989), the Federal Circuit, in reversing a Board's 35 U.S.C. § 112, first paragraph rejection, held that there was adequate written description support for applicant's claim limitation, despite the fact that it was not set forth "*in haec verba*" (i.e., "in these words" or "verbatim") in the specification.

> sufficiently present at a target site to provide therapeutic effects for a particular disease or disorder *in vivo* via various administration routes. The specification also fails to provide adequate guidance for the correlation between the cell-specific expressed gene product and a particular disease or disorder.

Applicants respectfully traverse and will first discuss claims 1-6, 8, and 9, which are drawn to a retroviral vector. The Specification discloses *in vitro* uses of the viral vector, e.g., to transiently transect cell lines and to express a recombinant protein at a high level in particular cell lines. See, e.g., page 17, line 23 through page 18, line 23.

In this connection, Applicants would like to remind the Examiner of "TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH-ENABLEMENT OF CHEMICAL/BIOTECHNICAL APPLICATIONS" http://www.uspto.gov/web/offices/pac/dapp/1pecba.htm ("Training Materials"). Example G of the Training Materials illustrates a hypothetical situation that mirrors the present case. As in Example G, claims 1-6, 8, and 9 are drawn to a viral vector and "[t]he specification discloses an *in vitro* use for the viral vector of [the claims] and clearly discloses how to make and use the viral vector in the *in vitro* environment." As also in Example G, the "claim[s do] not recite any environment of use." Example G further provides the following guidance to Examiners:

> only one enabled use covering the scope of the claim[s] is needed to enable the claim[s]. Therefore, the disclosure with respect to the *in vitro* use of the viral vector is sufficient to enable [the claims] and it would be inappropriate to include [the claims] in a rejection under 35 U.S.C. 112, first paragraph.

In view of the very clear guidelines in the Training Materials and the teachings in the Specification, Applicants submit that claims 1-6, 8, and 9 meet the enablement requirement. For the same reasons, claims 10-12, 20, and 21, which depend from claim 1, also meet the enablement requirement.

CONCLUSION

Applicants submit that grounds for rejection asserted by the Examiner have been overcome, and that the claims, as pending, define subject matter that is definite and enabled. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

Enclosed is Petition for Three Month Extension of Time fee and a Notice of Appeal. Please apply the required fees of $490 and $170, and any other charges or credits to deposit account 06-1050, referencing attorney docket 10737-006001.

Respectfully submitted,

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